2009

Dianna Espinoza and Paige Hunsaker v. Gold Cross Service, Inc. : Brief of Appellee

Utah Court of Appeals

Roger H. Hoole; Hoole and King, L.C.; Attorney for Appellant.
Alan L. Sullivan; Amber M. Mettler; Snell and Wilmer L.L.P.; Attorneys for Appellee.

IN THE UTAH COURT OF APPEALS

DIANNA ESPINOZA and PAIGE HUNSAKER, Plaintiffs/Appellants, v. GOLD CROSS SERVICE, INC., d.b.a. GOLD CROSS AMBULANCE, Defendant/Appellee.	No. 20090011

BRIEF OF APPELLEE

Appeal from Judgment Granting Defendant's Motion for Summary Judgment and Denying Plaintiffs' Cross-Motions for Summary Judgment by the Third Judicial District Court, Salt Lake County, Honorable L.A. Dever, District Court Case No. 060903237

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Federal Cases

State Cases

Federal Statutes

State Rules

Federal Regulations

STATEMENT OF THE ISSUES AND STANDARD OF REVIEW

In this appeal, Appellants Paige Hunsaker and Dianna Espinoza (collectively, "Appellants") contend that Gold Cross Services, Inc. ("Gold Cross") violated federal medical privacy regulations when it charged $30 to release copies of Appellants' medical records to Appellants' attorney and that Gold Cross is therefore liable to Appellants under a theory of unjust enrichment.

Pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the United States Department of Health and Human Services ("DHHS") promulgated regulations governing the use and disclosure of personal medical records by "covered entities." See 45 C.F.R. §§ 164.500-.534 (2005). Under these regulations, an individual is permitted nearly unfettered access to his or her private medical records (i.e., protected health information). See id. at § 164.502(a)(1)(i); Standards for Privacy of Individually Identifiable Health Information (the "HIPAA Privacy Rule"), 65 Fed. Reg. 82,462, 82,499 (Dec. 28, 2000). DHHS regulations state that "[i]f the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity . . . . may impose a reasonable, cost-based fee" that includes, in relevant part, only the cost of copying and postage. 45 C.F.R. § 164.524(c), (c)(4); see also 65 Fed. Reg. at 82,557. This fee limitation provision does not apply to "anyone other than the individual" who is the subject of the requested medical records. 65 Fed. Reg. at 82,557.

In 2006, Appellants filed nearly identical complaints against Gold Cross alleging a variety of state law claims based on the theory that Gold Cross violated the DHHS

regulations by charging more than the reasonable cost of copying and postage to release Appellants' medical records to their attorney. (Hunsaker R. 1-8, Espinoza R. 1-9.)

In their appeal, Appellants seek reversal of the District Court's decision granting summary judgment to Gold Cross and denying Appellants' cross-motion for summary judgment. (Appellants' Opening Brief ("AOB") at 14.) The District Court concluded that the undisputed facts showed that Appellants did not request their medical records as "individuals" under the DHHS regulations, and therefore, Gold Cross was permitted to charge more than the cost of copying and mailing to release the records. (See Espinoza R. 490-92 (12/9/08 Minute Entry), AOB at 1, 24.)

Issue: Whether Appellants may maintain a claim for unjust enrichment based on an allegation that Gold Cross violated the HIPAA regulations when it charged $30 to release copies of Appellants' medical records to Appellants' counsel where DHHS has interpreted the regulations as mandating a lower fee only when medical records are released to the patient directly.

Standard of Review: Questions of statutory interpretation are questions of law. See ABCO Enters. v. Utah State Tax Comm'n, 2009 UT 36, ¶ 7, 211 P.3d 382, 385. The Court reviews "trial court's legal conclusions and ultimate grant or denial of summary judgment for correctness . . . viewing the facts and all reasonable inferences drawn there from in the light most favorable to the nonmoving party." Bahr v. Imus, 2009 UT App 155, ¶ 5, 211 P.3d 987, 989 (quotation and alteration omitted).

DETERMINATIVE PROVISIONS

The determinative provision is 45 C.F.R. § 164.524(c)(4), which DHHS adopted pursuant to HIPAA. See generally Pub. L. 104-191, 110 Stat. 1936 (codified primarily in Titles 18, 26, and 42 of the U.S. Code). Specifically, the relevant provisions within HIPAA are found at 42 U.S.C. § 1320d to d-8. All determinative provisions and the cited sections from 45 C.F.R. parts 160 and 164 are attached to this brief as Addendum A.

STATEMENT OF THE CASE

I. NATURE OF THE CASE AND COURSE OF PROCEEDINGS

This appeal involves the interpretation of a federal regulation issued pursuant to HIPAA, 45 C.F.R. § 164.524(c)(4).

On February 23, 2006, Appellants separately filed suit against Gold Cross alleging that Gold Cross violated 45 C.F.R. § 164.524(c)(4) by charging $30 to release Appellants' medical records to Appellants' counsel. Based on this allegation, Appellants asserted claims for: (1) violation of the Utah Sales Practices Act; (2) breach of contract; and (3) unjust enrichment. (Hunsaker R. 1-8, Espinoza R. 1-9.) After exchanging written discovery, Gold Cross moved for summary judgment on all claims in both cases. (Hunsaker R. 84-98, Espinoza R. 91-107.) Appellants abandoned their contract claims, but cross-moved for summary judgment on their remaining two claims. (Hunsaker R. 491 ("Plaintiff now agrees with Defendant that there was no agreement between them and that, therefore, there could have been no breach of contract."), Espinoza R. 123 (same).)

After the parties' cross-motions for summary judgment were fully briefed, Gold Cross moved to consolidate the two cases. (Hunsaker R. 260-472, Espinoza R. 267-477.) The District Court granted Gold Cross's motion on September 29, 2008, and consolidated the two cases into Espinoza v. Gold Cross Services, Inc., Case No. 060903237. (Espinoza R. 483-84.)

Thereafter, on December 9, 2008, the District Court granted Gold Cross's Motion for Summary Judgment and denied Appellants' cross-motion. (Espinoza R. 490-93.) The Court ruled that the undisputed facts show that Appellants did not request their medical records as "individuals," and that Appellants' position is contrary to the established position of the United States Department of Health and Human Services. (Espinoza R. 490-93.)

On appeal, Appellants challenge the District Court's ruling only with respect to their claim for unjust enrichment. (AOB at 1 n.1.) Appellants contend that (1) "material facts exist which contradict the trial court's conclusion that" Appellants did not request their medical records from Gold Cross as individuals and (2) the "undisputed facts show that Gold Cross was unjustly enriched" by charging $30 to release Appellants' medical records. (AOB at 15, 21.)

II. STATEMENT OF FACTS

Gold Cross is a licensed ambulance service provider with a long history of providing ambulance service to Salt Lake County, Utah. (Hunsaker R. 86, 107, Espinoza R. 94, 112.) On October 21, 2003, Gold Cross provided ambulance services to Ms. Espinoza. (Espinoza R. 2.) On January 5, 2004, Gold Cross provided ambulance

services to Ms. Hunsaker. (Hunsaker R. 2.) In both instances, Gold Cross compiled medical records related to the Appellants' ambulance transportation. (Id.)

Subsequently, Gold Cross received signed and notarized forms entitled "Patient's Authorization to Release Health Information to Patient" (hereinafter, "Patient Authorization Forms") directing Gold Cross to provide copies of Ms. Espinoza's and Ms. Hunsaker's medical records to their attorney. (Hunsaker R. 2-3, Espinoza R. 2-3.) Specifically, the Patient Authorization Forms requested that Gold Cross mail Appellants' medical records to Roger H. Hoole, Appellants' attorney. (See, e.g., Hunsaker R. 11 (Ex. A), Espinoza R. 12 (Ex. A).) In response to these requests, Gold Cross contacted Appellants' attorney and informed him that it would send the medical records after it received payment in the amount of $30. (Hunsaker R. 3, Espinoza R. 3.) Gold Cross received a payment of $30 from Ms. Espinoza on April 28, 2004, made "under protest," and a payment of $30 from Ms. Hunsaker on October 27, 2005, also made "under protest." (Hunsaker R. 4, Espinoza R. 4.) After receiving these payments, Gold Cross promptly provided copies of Appellants' medical records to their attorney. (Id.)

There is no dispute as to any of the foregoing facts. Appellants contend that because they requested their medical records for their use and directed that these records be sent to them at their attorney's office, they were the "intended recipients" of the request to Gold Cross and, therefore, Appellants requested their medical records as individuals under the applicable DHHS regulations. (AOB at 6, 14.) This, however, is not a disputed question of fact; the nature of Appellants' request to Gold Cross under the DHHS regulations is a question of law. Not only is it a question of law, it is a question of

federal law, the enforcement of which is left only to the Secretary of Health and Human Services. See Acara v. Banks, 470 F.3d 569, 571 (5th Cir. 2006). And it is a question of federal law that the Secretary has already answered just as the District Court did here, something that is notably absent in the opening brief.

SUMMARY OF THE ARGUMENT

Appellants contend that Gold Cross Services violated the DHHS regulations when it charged $30 to release copies of Appellants' medical records to Appellants' attorney and that Gold Cross should be liable to Appellants under their claims of unjust enrichment. The federal statute and regulations at issue, however, do not provide for any private right of action and specifically delegate enforcement of the regulations to the Secretary of Health and Human Services. Appellants ask this Court to interpret these regulations in a manner that is directly contrary to the statute and the position of DHHS.

On the one hand, Appellants contend that outstanding factual issues precluded the District Court from determining that Appellants were not requesting their medical records from Gold Cross as individuals, and therefore, Gold Cross violated the DHHS regulations. (AOB at 20.) On the other hand, Appellants argue that the "undisputed facts show that Gold Cross was unjustly enriched" and that, therefore, the District Court should have granted Appellants' cross-motion for summary judgment on their unjust enrichment claims. (AOB at 21.) Appellants cannot have it both ways.

It is clear from the record that, as the District Court recognized, there is no dispute as to any fact – material or otherwise. Thus, all that remains is a question of law – a question of federal law. And based on the case law and the governing agency's own

interpretations of its regulations, Gold Cross did not violate the DHHS regulations when it charged Appellants $30 to release copies of their medical records to their attorney. Even supposing, however, that Gold Cross did violate these regulations, Appellants' claims still fail. As a threshold matter, HIPAA does not provide a private right of action and, in fact, explicitly delegates enforcement to the Secretary of Health and Human Services.

Beyond that, Appellants cannot satisfy the elements of a claim for unjust enrichment for two reasons. First, Appellants admit that there was never any contract, agreement, or similar understanding between Appellants and Gold Cross that Gold Cross would charge anything less than $30 to provide Appellants' medical records to Appellants' attorney. Rather, the entire basis of Appellants' unjust enrichment claim is whether Gold Cross complied with HIPAA and its regulations – this is not a proper basis for an unjust enrichment claim. Second, it is not inequitable or unjust to allow Gold Cross to retain any benefit that might have resulted from Appellants' $30 payments given that Appellants knowingly paid this amount "under protest" and elected not to pursue the administrative remedy provided by federal law.

This Court should affirm.

ARGUMENT

I. GOLD CROSS COMPLIED WITH ALL APPLICABLE FEDERAL REGULATIONS.

The DHHS regulations adopted pursuant to HIPAA govern the obligation of "covered entities" to provide access to individuals' medical records.[1] Under these regulations, "an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set." 45 C.F.R. § 164.524(a)(1). The DHHS regulations further provide that "if the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity . . . . may impose a reasonable, cost-based fee" that includes, in relevant part, the cost of copying and postage. 45 C.F.R. § 164.524(c)(4) (emphasis added). This fee limitation provision does not apply to "anyone other than the individual" who is the subject of the requested medical records. 65 Fed. Reg. at 82,557.

Appellants do not dispute the foregoing. Rather, Appellants contend that because they purportedly "requested" their medical records to be provided to them – albeit at their attorney's office – Appellants personally requested their records and therefore the fee limitation provision in the DHHS regulations should apply. (AOB at 15-16.) This argument, however, is directly contrary to the position of DHHS, as noted by the District

[1] A covered entity is defined as: "(1) a health plan; (2) a health care clearinghouse; or (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter." 45 C.F.R. § 160.103. Gold Cross is a covered entity.

Court. (Espinoza R. 490-91.) In the commentary that accompanied publication of the amended regulations in 2002, DHHS observed that the provision

> limits only the fees that may be charged to individuals, or to their personal representatives in accordance with § 164.502(g), when the request is to obtain a copy of protected health information about the individual in accordance with the right of access. The fee limitations in § 164.524(c)(4) do not apply to any other permissible disclosures by the covered entity, including disclosures that are based on an individual's authorization that is valid under § 164.508, or other disclosures permitted without the individual's authorization as specified in § 164.512.

HIPAA Privacy Rule, 67 Fed. Reg. 53,182, 53,254 (Aug. 14, 2002) (emphases added). The DHHS regulations define a "personal representative" to include persons who, "under applicable law" have the "authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care" or with respect to minors. 45 C.F.R. § 164.502(g)(2). An attorney may or may not be an individual's "personal representative" for purposes of the DHHS regulations. See 65 Fed. Reg. at 82,651 ("For example, an attorney of an individual may or may not be a personal representative under the rule depending on the attorney's authority to act on behalf of the individual in decisions related to health care."). Appellants have never claimed that their attorney was acting as their "personal representative" as used in 45 C.F.R. § 164.502(g)(2). (See, e.g., Hunsaker R. 350, Espinoza R. 135.)

The fee limitation is thus available to the patient herself but not to an attorney who seeks the patient's records based on that patient's authorization – which is exactly what

happened here.[2] As one court has held: "Although nothing in the regulations prevents a law firm from drafting or mailing the request for records on behalf of its clients, or from directing that the records be sent to its office, we hold nonetheless that the HIPAA regulations require the reduced rate only when the individual himself requests the records." Webb v. Smart Document Solutions, LLC, 499 F.3d 1078, 1080 (9th Cir. 2007); see also Bugarin v. ChartOne, Inc., 38 Cal. Rptr. 3d 505, 510 (Cal. Ct. App. 2006) (concluding law firm is not entitled to reduced fee).

Appellants argue that the Ninth Circuit's opinion in Webb is distinguishable because in that case the lawyers requested the patient's medical records. (AOB at 17.) Those are exactly our facts here. In any event, the court in Webb was not suggesting that an individual may have records sent to her at her attorney's office and still qualify for the reduced rate. See Webb, 499 F.3d at 1089. To the contrary, the court noted that because of privacy concerns "it makes sense to make it more difficult for third parties to obtain records, even with authorization." Id. This is consistent with one of the major purposes of the DHHS regulations – "[t]o protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information." 65 Fed. Reg. at 82,465; see also Bugarin, 38 Cal. Rptr. 3d at 508. Privacy concerns arise only when records are provided to someone other than the individual who is the subject of those records. See Bugarin, 38 Cal. Rptr. 3d at 509-10. Thus, for example, covered entities must require third parties (such as Appellants'

[2] See also 45 C.F.R. § 164.502(a)(1) (distinguishing between permitted disclosures to the individual and disclosures pursuant to a valid authorization); id. at § 164.524(b) (no authorization required for an individual's request to access her own records).

attorney) to have valid patient authorizations in order to obtain access to an individual's medical records. See id.; 45 C.F.R. § 164.508. This makes sense because concerns about ease of access (i.e., cost) by an individual are not implicated when medical records are being provided to third parties (such as Appellants' attorney). See Bugarin, 38 Cal. Rptr. 3d at 509-10. Accordingly, covered entities like Gold Cross may charge those third parties more than the cost of copying and postage when records are sent to someone other than the individual or that individual's "personal representative." See id. at 510.

In short, there is no dispute as to the contents of the Patient Authorization Forms, which directed Gold Cross to send Appellants' medical records to their attorney, rather than to Appellants themselves. (Hunsaker R. 11 (Ex. A), Espinoza R. 12 (Ex. A).) This is not a request by an individual to gain access to her own records and, therefore, the fee limitation provision does not apply. See 67 Fed. Reg. at 53,254 ("The fee limitations in § 164.524(c)(4) do not apply to . . . disclosures that are based on an individual's authorization that is valid under § 164.508, or other disclosures permitted without the individual's authorization as specified in § 164.512."); see also Bugarin, 38 Cal. Rptr. 3d at 510. Because Gold Cross was directed to disclose Appellants' medical records to someone other than to the Appellants themselves or to their personal representatives, Gold Cross acted in accordance with federal law when it charged $30.

II. APPELLANTS' CLAIMS FOR UNJUST ENRICHMENT FAIL AS A MATTER OF LAW.

Even if Gold Cross had violated the DHHS regulations when it charged $30 to release Appellants' medical records to Appellants' attorney, Appellants' unjust

enrichment claims fail as a matter of law for at least two reasons. First, all courts that have considered this issue have concluded that there is no private right of action under HIPAA. Irrespective of how it may be characterized, the sole factual basis for Appellants' only remaining cause of action (unjust enrichment) is an alleged violation of the DHHS regulations. This is contrary to the regulatory scheme set up by Congress and not permitted. Second, Appellants cannot, in any event, satisfy the elements of a claim for unjust enrichment because Appellants admit they never had any contract, agreement, or understanding – express or implied – with Gold Cross, and there is nothing inequitable about Gold Cross's alleged conduct. Simply put, Appellants elected not to file a complaint with the Secretary of Health and Human Services – the only remedy made available by Congress. Appellants' choice to waive their legal right to pursue reimbursement with the Secretary does not render Gold Cross's "enrichment" unjust.

A. There Is No Private Cause of Action to Enforce an Individual's Rights Under HIPAA.

Universally, courts have held that HIPAA does not contain a private right of action. See Johnson v. Quander, 370 F. Supp. 2d 79, 99-100 (D.D.C. 2005) ("While only a handful of courts have examined whether a private right of action is implied under the HIPAA, each Court has rejected the position."); see also 65 Fed. Reg. 82,601 (Dec. 28, 2000) ("Under HIPAA, individuals do not have a right to court action.").[3] The

[3] The only cases to substantively address Appellants' specific HIPAA allegations (i.e., a violation of the fee limitation provision in the DHHS regulations) were brought under a California law that broadly provides relief for violations of federal law. See Webb, 499 F.3d at 1082 (Section 17200 "is a broad statute designed to remedy violations of other laws, both state and federal"); Bugarin, 38 Cal. Rptr. 3d at 507.

appropriate avenue for relief for an aggrieved individual is to file a complaint with the Secretary of Health and Human Services. 45 C.F.R. § 160.306(a). In addition, HIPAA explicitly preempts "any contrary provision of State law." 42 U.S.C. § 1320d-7(a)(1); see also 45 C.F.R. §§ 160.202, 203.[4]

The sole factual predicate for Appellants' claims of unjust enrichment is an alleged HIPAA violation.[5] (Hunsaker R. 1-8, Espinoza R. 1-9.) A state law claim based upon a HIPAA violation is contrary to HIPAA because HIPAA recognizes an exclusive remedy under federal law and, therefore, the state law claim is preempted. Fisher v. Yale Univ., 2006 WL 1075035, at *3-4 (Conn. Super. Ct. Apr. 3, 2006) (State law claim against a hospital brought under the Connecticut Unfair Practices Act is preempted by HIPAA)[6]; see also Union Tel. Co. v. Qwest Corp., 495 F.3d 1187, 1197 (10th Cir. 2007) (concluding that allowing plaintiff to recover damages under a theory of unjust enrichment or quantum meruit frustrates the federal regulatory mechanism); Peach v.

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[4] The DHHS regulations define "State law" to mean "a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law." 45 C.F.R. § 160.202 (emphasis added).

[5] In addition, although Appellants attempt to characterize their claim as an equitable one, it is arguable that their claimed damages – $30 (less than the reasonable cost of copying and mailing) – would actually be a legal remedy, if such a remedy were allowed by HIPAA. Cf. Buckner v. Kennard, 2004 UT 78, ¶¶ 56-57, 99 P.3d 842, 857-58 (concluding that although plaintiffs characterized claim as an equitable one, the remedy they were seeking – back pay – is ordinarily considered a legal remedy comparable to money damages).

[6] The Connecticut court had asked the parties to submit supplemental briefing solely on the question: "To what extent, if any, has HIPAA pre-empted the right of a private individual to bring a CUTPA action in Connecticut (or an action under an analogous statute in another jurisdiction) for a violation of the provisions of HIPAA?" Fisher v. Yale Univ., 2006 WL 1075035, at *1 (Conn. Super. Ct. Apr. 3, 2006). In the course of its decision, the court noted, among other things, that "no sister state has found a CUTPA or similar cause of action, statutory or otherwise, for a HIPAA violation." Id. at *5.

Ultramar Diamond Shamrock, 229 F. Supp. 2d 759, 771 (E.D. Mich. 2002) (because claim for unjust enrichment is "merely a recharacterization of the claim for benefits" it is "barred by the preemptive effect of ERISA's legislative scheme"). Because Appellants' claims for unjust enrichment are premised only on an alleged HIPAA violation, the claims are contrary to, and therefore prohibited by, HIPAA.

To the extent Appellants believe they were harmed by Gold Cross's act of charging $30, allegedly in violation of the DHHS regulations, the appropriate (and only) avenue for seeking relief was to file a complaint with the Secretary of Health and Human Services. See 45 C.F.R. § 160.306(a) ("A person who believes a covered entity is not complying with the administrative simplification provisions may file a complaint with the Secretary."); see also Acara v. Banks, 470 F.3d 569, 571 (5th Cir. 2006) ("HIPAA limits enforcement of the statute to the Secretary of Health and Human Services"). The Secretary may choose to initiate an investigation. See 45 C.F.R. § 160.306(c). If the Secretary chooses to investigate and if that investigation indicates there was noncompliance, the Secretary may resolve the matter informally. Id. at § 160.312(a)(1). Alternatively, the Secretary may, after allowing the covered entity an opportunity to submit written evidence of any mitigating factors or affirmative defenses, impose a civil monetary penalty. Id. at § 160.312(a)(3). Appellants elected not to pursue their remedy.

B. Appellants Cannot Maintain a Claim for Unjust Enrichment.

Even if Appellants could overcome the foregoing legal impediments, Appellants' claims for unjust enrichment suffer from at least two additional fatal flaws. For unjust enrichment to serve as a basis for recovery, there must be "(1) a benefit conferred on one

person by another; (2) an appreciation or knowledge by the conferee of the benefit; and (3) the acceptance or retention by the conferee of the benefit under such circumstances as to make it inequitable for the conferee to retain the benefit without payment of its value." American Towers Owners Ass'n, Inc. v. CCI Mech., Inc., 930 P.2d 1182, 1192 (Utah 1996).

First, Appellants' unjust enrichment claims are based entirely on whether Gold Cross charged the amount permitted by the DHHS regulations. This is not an unjust enrichment claim. A claim for unjust enrichment is also known as "quasi-contract" or "contracts implied in law" and requires the remedy of restitution. See, e.g., Knight v. Post, 748 P.2d 1097, 1100 (Utah Ct. App. 1988). Appellants, however, have admitted that "there was no agreement" between the parties and that Gold Cross never agreed to supply medical records for anything less than $30. (Hunsaker R. 340, 349, Espinoza R. 345, 354.) Without such an agreement – express or implied, understanding, or even a promise between the parties, Appellants cannot bring a claim for quasi-contract or unjust enrichment. See Knight, 748 P.2d at 1101 (Plaintiff "failed to show that there is either an express or implied contract . . . on which he may base recovery"). Violation of a statute or regulation (particularly when there is no private right of action under that statute or regulation) is simply not a basis for an unjust enrichment claim.

Second, for liability to be found under a theory of "quasi-contract, unjust enrichment, or restitution," "[t]here must be some misleading act, request for services, or the like, to support such an action." Knight, 748 P.2d at 1101 (emphasis and quotation omitted). Not only do Appellants fail even to identify an alleged misleading act or

request for services, they affirmatively admit that Gold Cross never agreed to supply their medical records for anything less than $30. (Hunsaker R. 349, Espinoza R. 354.) This shows that to the extent one could construe the existence of some sort of implied contract between the parties, both sides got exactly what they bargained for. See Comet Theatre Enters., Inc. v. Cartwright, 195 F.2d 80, 83 (9th Cir. 1952) ("There is no equitable reason for invoking restitution when the plaintiff gets the exchange which he expected."). Therefore, even if Appellants could show that Gold Cross violated the DHHS regulations (which they cannot), Appellants cannot show that it would be inequitable for Gold Cross to retain whatever "benefit" it received from Appellants because Appellants do not allege that they were ever deceived or misled by Gold Cross. See Knight, 748 P.2d at 1101; see also Commercial Fixtures and Furnishings, Inc. v. Adams, 564 P.2d 773, 774 (Utah 1977).

In fact, Appellants appear to argue that it would be inequitable or unjust to allow Gold Cross to keep the $30 Appellants knowingly paid "under protest" (i.e., Appellants never believed that Gold Cross had agreed to charge otherwise) and for which Appellants declined to pursue the administrative remedy provided in the same federal regulations that Appellants now contend Gold Cross violated. Appellants make this claim despite the fact that Appellants' attorney could simply have declined to pay the $30 and instructed his clients to request that their medical records be released to them directly. (Hunsaker R. 162, Espinoza R. 226 ("Gold Cross admits that it does not charge individuals any per page fee when releasing an individual's medical records directly to that individual.").)

> The simple and direct alternative that is open to [plaintiff] is

> to request his own medical records from his provider and, having received them, hand them to his lawyer. The rules that require this slightly circuitous procedure are in place to protect individual privacy; the very minor inconvenience of asking for one's own records is a small price to pay for rules that protect the privacy of medical records.

Bugarin, 38 Cal. Rptr. 3d at 510. Instead, Appellants knowingly paid the $30 "under protest," elected not to file a complaint with the Secretary of Health and Human Services, and filed suit in State court – seeking, of course, monetary damages well in addition to the $30 payments at issue. Appellants' choice does not make Gold Cross's conduct – even if it was in violation of the DHHS regulations – inequitable or unjust.

For all of the foregoing reasons, Appellants' claims for unjust enrichment fail and the judgment of the District Court must be affirmed.

CONCLUSION

Because Gold Cross complied with all applicable federal regulations, the judgment of the District Court should be affirmed. Even if, however, Gold Cross did violate these regulations, Appellants' claims for unjust enrichment fail because there is no private right of action for a HIPAA violation and such a claim is contrary to and preempted by federal law. Moreover, to the extent they have even attempted to satisfy the elements of a claim for unjust enrichment, Appellants cannot do so. There was never any contract, agreement, or understanding between Appellants and Gold Cross and there is nothing inequitable or unjust about allowing Gold Cross to retain whatever benefit accrued from Appellants' knowing $30 payment made "under protest."

For all of the foregoing reasons, the judgment of the District Court should be AFFIRMED.

REQUEST FOR COSTS AND ATTORNEYS' FEES

Because Appellants' arguments lack any factual or legal support, their appeal is frivolous and Gold Cross is entitled to damages. Under Utah Rule of Appellate Procedure 33, "[i]f an appeal is found to be frivolous, the court must award damages." Utah R. App. P. 33 advisory committee's note. A frivolous appeal is "one that is not grounded in fact, not warranted by existing law, or not based on a good faith argument to extend, modify, or reverse existing law." Utah R. App. P. 33(b). Because the arguments Appellants made are without any merit and have no reasonable likelihood of prevailing, the Court should award Gold Cross damages pursuant to Rule 33. See Porco v. Porco, 752 P.2d 365, 369 (Utah Ct. App. 1988).

DATED this 5th day of October, 2009.

SNELL & WILMER L.L.P.

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Amber M. Mettler
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CERTIFICATE OF SERVICE

This is to certify that on the 5th day of October, 2009, two true and correct copies of BRIEF OF APPELLEE were sent via U.S. Mail, postage prepaid, to:

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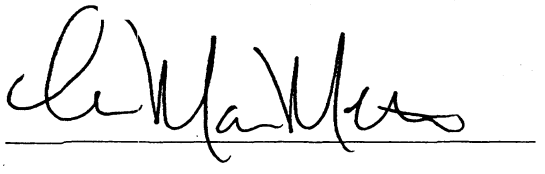

Tab A

42 U.S.C. § 1320d

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d. Definitions

For purposes of this part:

(1) Code set

The term ``code set'' means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

(2) Health care clearinghouse

The term ``health care clearinghouse'' means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

(3) Health care provider

The term ``health care provider'' includes a provider of services (as defined in section 1395x(u) of this title), a provider of medical or other health services (as defined in section 1395x(s) of this title), and any other person furnishing health care services or supplies.

(4) Health information

The term ``health information'' means any information, whether oral or recorded in any form or medium, that--

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

(5) Health plan

The term ``health plan'' means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 300gg-91 of this title). Such term includes the following, and any combination thereof:

(A) A group health plan (as defined in section 300gg-91(a)

of this title), but only if the plan--

(i) has 50 or more participants (as defined in section 1002(7) of title 29); or

(ii) is administered by an entity other than the employer who established and maintains the plan.

(B) A health insurance issuer (as defined in section 300gg-91(b) of this title).

(C) A health maintenance organization (as defined in section 300gg-91(b) of this title).

(D) Parts \1\ A, B, or C of the Medicare program under subchapter XVIII of this chapter.

\1\ So in original. Probably should be ``Part''.

(E) The medicaid program under subchapter XIX of this chapter.

(F) A Medicare supplemental policy (as defined in section 1395ss(g)(1) of this title).

(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

(I) The health care program for active military personnel under title 10.

(J) The veterans health care program under chapter 17 of title 38.

(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10.

(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5.

(6) Individually identifiable health information

The term ``individually identifiable health information'' means any information, including demographic information collected from an individual, that--

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and--

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(7) Standard

The term ``standard'', when used with reference to a data

element of health information or a transaction referred to in section 1320d-2(a)(1) of this title, means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1320d-1 through 1320d-3 of this title.

(8) Standard setting organization

The term ``standard setting organization'' means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1171, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2021; amended Pub. L. 107-105, Sec. 4, Dec. 27, 2001, 115 Stat. 1007.)

References in Text

The Indian Health Care Improvement Act, referred to in par. (5)(L), is Pub. L. 94-437, Sept. 30, 1976, 90 Stat. 1400, as amended, which is classified principally to chapter 18 (Sec. 1601 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

Prior Provisions

A prior section 1171 of act Aug. 14, 1935, was classified to section 1320c-20 of this title prior to repeal by Pub. L. 97-35.

Amendments

2001--Par. (5)(D). Pub. L. 107-105 substituted ``Parts A, B, or C'' for ``Part A or part B''.

Purpose

Section 261 of title II of Pub. L. 104-191 provided that: ``It is the purpose of this subtitle [subtitle F (Secs. 261-264) of title II of Pub. L. 104-191, enacting this part, amending sections 242k and 1395cc of this title, and enacting provisions set out as a note under section 1320d-2 of this title] to improve the Medicare program under title XVIII of the Social Security Act [subchapter XVIII of this chapter], the medicaid program under title XIX of such Act [subchapter XIX of this chapter], and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.''

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-1. General requirements for adoption of standards

(a) Applicability

Any standard adopted under this part shall apply, in whole or in part, to the following persons:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1320d-2(a)(1) of this title.

(b) Reduction of costs

Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) Role of standard setting organizations

(1) In general

Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) Special rules

(A) Different standards

The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if--

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5.

(B) No standard by standard setting organization

If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part--

(i) paragraph (1) shall not apply; and

(ii) subsection (f) of this section shall apply.

(3) Consultation requirement

(A) In general

A standard may not be adopted under this part unless--

(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f) of this section, consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) Organizations described

The organizations referred to in subparagraph (A) are the following:

(i) The National Uniform Billing Committee.

(ii) The National Uniform Claim Committee.

(iii) The Workgroup for Electronic Data Interchange.

(iv) The American Dental Association.

(d) Implementation specifications

The Secretary shall establish specifications for implementing each of the standards adopted under this part.

(e) Protection of trade secrets

Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

(f) Assistance to Secretary

In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 242k(k) of this title, and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

(g) Application to modifications of standards

This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1320d-3(b) of this title in the same manner as it applies to an initial standard adopted under section 1320d-3(a) of this title.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1172, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2023.)

Prior Provisions

A prior section 1172 of act Aug. 14, 1935, was classified to section 1320c-21 of this title prior to the general amendment of part B of this subchapter by Pub. L. 97-248.

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-2. Standards for information transactions and data elements

(a) Standards to enable electronic exchange

(1) In general

The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for--

(A) the financial and administrative transactions described in paragraph (2); and

(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

(2) Transactions

The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

(A) Health claims or equivalent encounter information.
(B) Health claims attachments.
(C) Enrollment and disenrollment in a health plan.
(D) Eligibility for a health plan.
(E) Health care payment and remittance advice.
(F) Health plan premium payments.
(G) First report of injury.
(H) Health claim status.
(I) Referral certification and authorization.

(3) Accommodation of specific providers

The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

(b) Unique health identifiers

(1) In general

The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan,

and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

(2) Use of identifiers

The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

(c) Code sets

(1) In general

The Secretary shall adopt standards that--

(A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) of this section from among the code sets that have been developed by private and public entities; or

(B) establish code sets for such data elements if no code sets for the data elements have been developed.

(2) Distribution

The Secretary shall establish efficient and low-cost procedures for distribution (including electronic distribution) of code sets and modifications made to such code sets under section 1320d-3(b) of this title.

(d) Security standards for health information

(1) Security standards

The Secretary shall adopt security standards that--

(A) take into account--

(i) the technical capabilities of record systems used to maintain health information;

(ii) the costs of security measures;

(iii) the need for training persons who have access to health information;

(iv) the value of audit trails in computerized record systems; and

(v) the needs and capabilities of small health care providers and rural health care providers (as such providers are defined by the Secretary); and

(B) ensure that a health care clearinghouse, if it is part of a larger organization, has policies and security procedures which isolate the activities of the health care clearinghouse with respect to processing information in a manner that prevents unauthorized access to such information by such larger organization.

(2) Safeguards

Each person described in section 1320d-1(a) of this title who

maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards--

(A) to ensure the integrity and confidentiality of the information;

(B) to protect against any reasonably anticipated--

(i) threats or hazards to the security or integrity of the information; and

(ii) unauthorized uses or disclosures of the information; and

(C) otherwise to ensure compliance with this part by the officers and employees of such person.

(e) Electronic signature

(1) Standards

The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1) of this section.

(2) Effect of compliance

Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1) of this section.

(f) Transfer of information among health plans

The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1173, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2024.)

Prior Provisions

A prior section 1173 of act Aug. 14, 1935, was classified to section 1320c-22 of this title prior to the general amendment of part B of this subchapter by Pub. L. 97-248.

Recommendations With Respect to Privacy of Certain Health Information

Pub. L. 104-191, title II, Sec. 264, Aug. 21, 1996, 110 Stat. 2033, provided that:

``(a) In General.--Not later than the date that is 12 months after the date of the enactment of this Act [Aug. 21, 1996], the Secretary of Health and Human Services shall submit to the Committee on Labor and Human Resources and the Committee on Finance of the Senate and the Committee on Commerce and the Committee on Ways and Means of the House of Representatives detailed recommendations on standards with respect to the privacy of individually identifiable health information.

``(b) Subjects for Recommendations.--The recommendations under subsection (a) shall address at least the following:

``(1) The rights that an individual who is a subject of individually identifiable health information should have.

``(2) The procedures that should be established for the exercise of such rights.

``(3) The uses and disclosures of such information that should be authorized or required.

``(c) Regulations.--

``(1) In general.--If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act [subsec. (a) of this section] (as added by section 262) is not enacted by the date that is 36 months after the date of the enactment of this Act [Aug. 21, 1996], the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act. Such regulations shall address at least the subjects described in subsection (b).

``(2) Preemption.--A regulation promulgated under paragraph (1) shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.

``(d) Consultation.--In carrying out this section, the Secretary of Health and Human Services shall consult with--

``(1) the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)); and

``(2) the Attorney General.''

Ex. Ord. No. 13181. To Protect the Privacy of Protected Health Information in Oversight Investigations

Ex. Ord. No. 13181, Dec. 20, 2000, 65 F.R. 81321, provided:

By the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, it is ordered as follows:

Section 1. Policy.

It shall be the policy of the Government of the United States that law enforcement may not use protected health information concerning an individual that is discovered during the course of health oversight activities for unrelated civil, administrative, or criminal investigations of a non-health oversight matter, except when the balance of relevant factors weighs clearly in favor of its use. That is, protected health information may not be so used unless the public interest and the need for disclosure clearly outweigh the potential for injury to the patient, to the physician-patient relationship, and to the treatment services. Protecting the privacy of patients' protected health information promotes trust in the health care system. It improves the

quality of health care by fostering an environment in which patients can feel more comfortable in providing health care professionals with accurate and detailed information about their personal health. In order to provide greater protections to patients' privacy, the Department of Health and Human Services is issuing final regulations concerning the confidentiality of individually identifiable health information under the Health Insurance Portability and Accountability Act of 1996 [Pub. L.

104-191, see Tables for classification] (HIPAA). HIPAA applies only to ``covered entities,'' such as health care plans, providers, and clearinghouses. HIPAA regulations therefore do not apply to other organizations and individuals that gain access to protected health information, including Federal officials who gain access to health records during health oversight activities.

Under the new HIPAA regulations, health oversight investigators will appropriately have ready access to medical records for oversight purposes. Health oversight investigators generally do not seek access to the medical records of a particular patient, but instead review large numbers of records to determine whether a health care provider or organization is violating the law, such as through fraud against the Medicare system. Access to many health records is often necessary in order to gain enough evidence to detect and bring enforcement actions against fraud in the health care system. Stricter rules apply under the HIPAA regulations, however, when law enforcement officials seek protected health information in order to investigate criminal activity outside of the health oversight realm.

In the course of their efforts to protect the health care system, health oversight investigators may also uncover evidence of wrongdoing unrelated to the health care system, such as evidence of criminal conduct by an individual who has sought health care. For records containing that evidence, the issue thus arises whether the information should be available for law enforcement purposes under the less restrictive oversight rules or the more restrictive rules that apply to non-oversight criminal investigations.

A similar issue has arisen in other circumstances. Under 18 U.S.C. 3486, an individual's health records obtained for health oversight purposes pursuant to an administrative subpoena may not be used against that individual patient in an unrelated investigation by law enforcement unless a judicial officer finds good cause. Under that statute, a judicial officer determines whether there is good cause by weighing the public interest and the need for disclosure against the potential for injury to the patient, to the physician-patient relationship, and to the treatment services. It is appropriate to extend limitations on the use of health information to all situations in which the government obtains medical records for a health oversight purpose. In recognition of the increasing importance of protecting health information as shown in the medical privacy rule, a higher standard than exists in 18 U.S.C. 3486 is necessary. It is, therefore, the policy of the Government of the United States that law enforcement may not use protected health information concerning an individual, discovered during the course of health oversight activities for unrelated civil, administrative, or criminal investigations, against that individual except when the balance of relevant factors weighs clearly in favor of its use. That is, protected health information may not be so used unless the public interest and the need for disclosure clearly outweigh the potential for injury to the patient, to the physician-patient relationship, and to the treatment services.

Sec. 2. Definitions.

(a) ``Health oversight activities'' shall include the oversight activities enumerated in the regulations concerning the confidentiality of individually identifiable health information promulgated by the Secretary of Health and Human Services pursuant to the ``Health Insurance Portability and Accountability Act of 1996,'' as amended [Pub. L. 104-191, see Tables for classification].

(b) ``Protected health information'' shall have the meaning ascribed to it in the regulations concerning the confidentiality of individually identifiable health information promulgated by the Secretary of Health and Human Services pursuant to the ``Health Insurance Portability and

Accountability Act of 1996,'' as amended.

(c) ``Injury to the patient'' includes injury to the privacy interests of the patient.

Sec. 3. Implementation.

(a) Protected health information concerning an individual patient discovered during the course of health oversight activities shall not be used against that individual patient in an unrelated civil, administrative, or criminal investigation of a non-health oversight matter unless the Deputy Attorney General of the U.S Department of Justice, or insofar as the protected health information involves members of the Armed Forces, the General Counsel of the U.S. Department of Defense, has authorized such use.

(b) In assessing whether protected health information should be used under subparagraph (a) of this section, the Deputy Attorney General shall permit such use upon concluding that the balance of relevant factors weighs clearly in favor of its use. That is, the Deputy Attorney General shall permit disclosure if the public interest and the need for disclosure clearly outweigh the potential for injury to the patient, to the physician-patient relationship, and to the treatment services.

(c) Upon the decision to use protected health information under subparagraph (a) of this section, the Deputy Attorney General, in determining the extent to which this information should be used, shall impose appropriate safeguards against unauthorized use.

(d) On an annual basis, the Department of Justice, in consultation with the Department of Health and Human Services, shall provide to the President of the United States a report that includes the following information:

(i) the number of requests made to the Deputy Attorney General for authorization to use protected health information discovered during health oversight activities in a non-health oversight, unrelated investigation;

(ii) the number of requests that were granted as applied for, granted as modified, or denied;

(iii) the agencies that made the applications, and the number of requests made by each agency; and

(iv) the uses for which the protected health information was authorized.

(e) The General Counsel of the U.S. Department of Defense will comply with the requirements of subparagraphs (b), (c), and (d), above. The General Counsel also will prepare a report, consistent with the requirements of subparagraphs (d)(i) through (d)(iv), above, and will forward it to the Department of Justice where it will be incorporated into the Department's annual report to the President.

Sec. 4. Exceptions.

(a) Nothing in this Executive Order shall place a restriction on the derivative use of protected health information that was obtained by a law enforcement agency in a non-health oversight investigation.

(b) Nothing in this Executive Order shall be interpreted to place a restriction on a duty imposed by statute.

(c) Nothing in this Executive Order shall place any additional limitation on the derivative use of health information obtained by the Attorney General pursuant to the provisions of 18 U.S.C. 3486.

(d) This order does not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the officers and employees, or any other person.

William J. Clinton.

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-3. Timetables for adoption of standards

(a) Initial standards

The Secretary shall carry out section 1320d-2 of this title not later than 18 months after Au

gust 21, 1996, except that standards relating to claims attachments shall be adopted not later than 30 months after August 21, 1996.

(b) Additions and modifications to standards

(1) In general

Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1320d-2 of this title, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

(2) Special rules

(A) First 12-month period

Except with respect to additions and modifications to code sets under subparagraph (B), the Secretary may not adopt any modification to a standard adopted under this part during the 12-month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

(B) Additions and modifications to code sets

(i) In general

The Secretary shall ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets.

(ii) Additional rules

If a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1174, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2026.)

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-4. Requirements

(a) Conduct of transactions by plans

(1) In general

If a person desires to conduct a transaction referred to in section 1320d-2(a)(1) of this title with a health plan as a standard transaction--

(A) the health plan may not refuse to conduct such transaction as a standard transaction;

(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction; and

(C) the information transmitted and received in connection with the transaction shall be in the form of standard data elements of health information.

(2) Satisfaction of requirements

A health plan may satisfy the requirements under paragraph (1) by--

(A) directly transmitting and receiving standard data elements of health information; or

(B) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse, and receiving *standard data elements through the health care clearinghouse*.

(3) Timetable for compliance

Paragraph (1) shall not be construed to require a health plan to comply with any standard, implementation specification, or modification to a standard or specification adopted or established by the Secretary under sections 1320d-1 through 1320d-3 of this title at any time prior to the date on which the plan is required to comply with the standard or specification under subsection (b) of this section.

(b) Compliance with standards

(1) Initial compliance

(A) In general

Not later than 24 months after the date on which an initial standard or implementation specification is adopted or established under sections 1320d-1 and 1320d-2 of this title, each person to whom the standard or implementation specification applies shall comply with the standard or specification.

(B) Special rule for small health plans

In the case of a small health plan, paragraph (1) shall be applied by substituting ``36 months'' for ``24 months''. For purposes of this subsection, the Secretary shall determine the plans that qualify as small health plans.

(2) Compliance with modified standards

If the Secretary adopts a modification to a standard or implementation specification under this part, each person to whom the standard or implementation specification applies shall comply with the modified standard or implementation specification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180-day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate.

(3) Construction

Nothing in this subsection shall be construed to prohibit any person from complying with a standard or specification by--

(A) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse; or

(B) receiving standard data elements through a health care clearinghouse.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1175, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2027.)

[[Page 1913]]

Extension of Deadline for Covered Entities Submitting Compliance Plans

Pub. L. 107-105, Sec. 2, Dec. 27, 2001, 115 Stat. 1003, provided that:

``(a) In General.--

``(1) Extension.--Subject to paragraph (2), notwithstanding section 1175(b)(1)(A) of the Social Security Act (42 U.S.C. 1320d-4(b)(1)(A)) and section 162.900 of title 45, Code of Federal Regulations, a health care provider, health plan (other than a small health plan), or a health care clearinghouse shall not be considered to be in noncompliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, before October 16, 2003.

``(2) Condition.--Paragraph (1) shall apply to a person

described in such paragraph only if, before October 16, 2002, the person submits to the Secretary of Health and Human Services a plan of how the person will come into compliance with the requirements described in such paragraph not later than October 16, 2003. Such plan shall be a summary of the following:

``(A) An analysis reflecting the extent to which, and the reasons why, the person is not in compliance.

``(B) A budget, schedule, work plan, and implementation strategy for achieving compliance.

``(C) Whether the person plans to use or might use a contractor or other vendor to assist the person in achieving compliance.

``(D) A timeframe for testing that begins not later than April 16, 2003.

``(3) Electronic submission.--Plans described in paragraph (2) may be submitted electronically.

``(4) Model form.--Not later than March 31, 2002, the Secretary of Health and Human Services shall promulgate a model form that persons may use in drafting a plan described in paragraph (2). The promulgation of such form shall be made without regard to chapter 35 of title 44, United States Code (commonly known as the `Paperwork Reduction Act').

``(5) Analysis of plans; reports on solutions.--

``(A) Analysis of plans.--

``(i) Furnishing of plans.--Subject to subparagraph (D), the Secretary of Health and Human Services shall furnish the National Committee on Vital and Health Statistics with a sample of the plans submitted under paragraph (2) for analysis by such Committee.

``(ii) Analysis.--The National Committee on Vital and Health Statistics shall analyze the sample of the plans furnished under clause (i).

``(B) Reports on solutions.--The National Committee on Vital and Health Statistics shall regularly publish, and widely disseminate to the public, reports containing effective solutions to compliance problems identified in the plans analyzed under subparagraph (A). Such reports shall not relate specifically to any one plan but shall be written for the purpose of assisting the maximum number of persons to come into compliance by addressing the most common or challenging problems encountered by persons submitting such plans.

``(C) Consultation.--In carrying out this paragraph, the National Committee on Vital and Health Statistics shall consult with each organization--

``(i) described in section 1172(c)(3)(B) of the Social Security Act (42 U.S.C. 1320d-1(c)(3)(B)); or

``(ii) designated by the Secretary of Health and Human Services under section 162.910(a) of title 45, Code of Federal Regulations.

``(D) Protection of confidential information.--

``(i) In general.--The Secretary of Health and Human Services shall ensure that any material provided under subparagraph (A) to the National Committee on Vital and Health Statistics or any organization described in subparagraph (C) is redacted so as to prevent the disclosure of any--

``(I) trade secrets;

``(II) commercial or financial information that is privileged or confidential; and

``(III) other information the disclosure of which would

constitute a clearly unwarranted invasion of personal privacy.

``(ii) Construction.--Nothing in clause (i) shall be construed to affect the application of section 552 of title 5, United States Code (commonly known as the `Freedom of Information Act'), including the exceptions from disclosure provided under subsection (b) of such section.

``(6) Enforcement through exclusion from participation in medicare.--

``(A) In general.--In the case of a person described in paragraph (1) who fails to submit a plan in accordance with paragraph (2), and who is not in compliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, on or after October 16, 2002, the person may be excluded at the discretion of the Secretary of Health and Human Services from participation (including under part C or as a contractor under sections 1816, 1842, and 1893) [42 U.S.C. 1395h, 1395u, 1395ddd] in title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

``(B) Procedure.--The provisions of section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) (other than the first and second sentences of subsection (a) and subsection (b)) shall apply to an exclusion under this paragraph in the same manner as such provisions apply with respect to an exclusion or proceeding under section 1128A(a) of such Act.

``(C) Construction.--The availability of an exclusion under this paragraph shall not be construed to affect the imposition of penalties under section 1176 of the Social Security Act (42 U.S.C. 1320d-5).

``(D) Nonapplicability to complying persons.--The exclusion under subparagraph (A) shall not apply to a person who--

``(i) submits a plan in accordance with paragraph (2); or

``(ii) who is in compliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, on or before October 16, 2002.

``(b) Special Rules.--

``(1) Rules of construction.--Nothing in this section shall be construed--

``(A) as modifying the October 16, 2003, deadline for a small health plan to comply with the requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations; or

``(B) as modifying--

``(i) the April 14, 2003, deadline for a health care provider, a health plan (other than a small health plan), or a health care clearinghouse to comply with the requirements of subpart E of part 164 of title 45, Code of Federal Regulations; or

``(ii) the April 14, 2004, deadline for a small health plan to comply with the requirements of such subpart.

``(2) Applicability of privacy standards before compliance deadline for information transaction standards.--

``(A) In general.--Notwithstanding any other provision of law, during the period that begins on April 14, 2003, and ends on October 16, 2003, a health care provider or, subject to subparagraph (B), a health care clearinghouse, that transmits any health information in electronic form in connection with a transaction described in subparagraph (C) shall comply with the

requirements of subpart E of part 164 of title 45, Code of Federal Regulations, without regard to whether the transmission meets the standards required by part 162 of such title.

``(B) Application to health care clearinghouses.--For purposes of this paragraph, during the period described in subparagraph (A), an entity that processes or facilitates the processing of information in connection with a transaction described in

subparagraph (C) and that otherwise would be treated as a health care clearinghouse shall be treated as a health care clearinghouse without regard to whether the processing or facilitation produces (or is required to produce) standard data elements or a standard transaction as required by part 162 of title 45, Code of Federal Regulations.

``(C) Transactions described.--The transactions described in this subparagraph are the following:

``(i) A health care claims or equivalent encounter information transaction.

``(ii) A health care payment and remittance advice transaction.

``(iii) A coordination of benefits transaction.

``(iv) A health care claim status transaction.

``(v) An enrollment and disenrollment in a health plan transaction.

``(vi) An eligibility for a health plan transaction.

``(vii) A health plan premium payments transaction.

``(viii) A referral certification and authorization transaction.

``(c) Definitions.--In this section--

``(1) the terms `health care provider', `health plan', and `health care clearinghouse' have the meaning given those terms in section 1171 of the Social Security Act (42 U.S.C. 1320d) and section 160.103 of title 45, Code of Federal Regulations;

``(2) the terms `small health plan' and `transaction' have the meaning given those terms in section 160.103 of title 45, Code of Federal Regulations; and

``(3) the terms `health care claims or equivalent encounter information transaction', `health care payment and remittance advice transaction', `coordination of benefits transaction', `health care claim status transaction', `enrollment and disenrollment in a health plan transaction', `eligibility for a health plan transaction', `health plan premium payments transaction', and `referral certification and authorization transaction' have the meanings given those terms in sections 162.1101, 162.1601, 162.1801, 162.1401, 162.1501, 162.1201, 162.1701, and 162.1301 of title 45, Code of Federal Regulations, respectively.''

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-5. General penalty for failure to comply with requirements and standards

(a) General penalty

(1) In general

Except as provided in subsection (b) of this section, the Secretary shall impose on any person who violates a provision of this part a penalty of not more than $100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

(2) Procedures

The provisions of section 1320a-7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1320a-7a of this title.

(b) Limitations

(1) Offenses otherwise punishable

A penalty may not be imposed under subsection (a) of this section with respect to an act if the act constitutes an offense punishable under section 1320d-6 of this title.

(2) Noncompliance not discovered

A penalty may not be imposed under subsection (a) of this section with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

(3) Failures due to reasonable cause

(A) In general

Except as provided in subparagraph (B), a penalty may not be imposed under subsection (a) of this section if--

(i) the failure to comply was due to reasonable cause and not to willful neglect; and

(ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) Extension of period

(i) No penalty

The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) Assistance

If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

(4) Reduction

In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) of this section that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1176, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2028.)

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-6. Wrongful disclosure of individually identifiable health information

(a) Offense

A person who knowingly and in violation of this part--

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual; or

(3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b) of this section.

(b) Penalties

A person described in subsection (a) of this section shall--

(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1177, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2029.)

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-7. Effect on State law

(a) General effect

(1) General rule

Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

(2) Exceptions

A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall not supersede a contrary provision of State law, if the provision of State law--

(A) is a provision the Secretary determines--

(i) is necessary--

(I) to prevent fraud and abuse;

(II) to ensure appropriate State regulation of insurance and health plans;

(III) for State reporting on health care delivery or costs; or

(IV) for other purposes; or

(ii) addresses controlled substances; or

(B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

(b) Public health

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

(c) State regulatory reporting

Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1178, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2029.)

References in Text

Section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (a)(2)(B), is section 264(c)(2) of Pub. L. 104-191, which is set out as a note under section 1320d-2 of this title.

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

Part C--Administrative Simplification

Sec. 1320d-8. Processing payment transactions by financial institutions

To the extent that an entity is engaged in activities of a financial institution (as defined in section 3401 of title 12), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.

(2) The request for, or the use or disclosure of, information by the entity with respect to a payment described in paragraph (1)--

(A) for transferring receivables;

(B) for auditing;

(C) in connection with--

(i) a customer dispute; or

(ii) an inquiry from, or to, a customer;

(D) in a communication to a customer of the entity regarding the customer's transactions, payment card, account, check, or electronic funds transfer;

(E) for reporting to consumer reporting agencies; or

(F) for complying with--

(i) a civil or criminal subpoena; or

(ii) a Federal or State law regulating the entity.

(Aug. 14, 1935, ch. 531, title XI, Sec. 1179, as added Pub. L. 104-191, title II, Sec. 262(a), Aug. 21, 1996, 110 Stat. 2030.)

45 C.F.R. 160
(Excerpts)

(b) To the extent required under the Social Security Act, 42 U.S.C. 1320a–7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in §164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in §164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

(1) Electronic storage media including memory devices in computers (hard

drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg–91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg–91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization

(including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg–91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq.*

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq.*

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq.*

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq.*

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg–91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)–(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the

past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002; 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003; 71 FR 8424, Feb. 16, 2006]

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002]

Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104–191.

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104–191, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under §160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at §160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the FEDERAL REGISTER. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at §160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C—Compliance and Investigations

SOURCE: 71 FR 8424, Feb. 16, 2006, unless otherwise noted.

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with, and the enforcement of, the applicable provisions of this part 160 and parts 162 and 164 of this subchapter.

§ 160.302 Definitions.

As used in this subpart and subparts D and E of this part, the following terms have the following meanings:

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d—1320d–4, 1320d–7, and 1320d–8;

(2) Section 264 of Pub. L. 104–191; or

(3) This subchapter.

ALJ means Administrative Law Judge.

Civil money penalty or *penalty* means the amount determined under § 160.404 of this part and includes the plural of these terms.

Respondent means a covered entity upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

Violation or *violate* means, as the context may require, failure to comply with an administrative simplification provision.

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable administrative simplification provisions.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable administrative simplification provisions.

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity is not complying with the administrative simplification provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable administrative simplification provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged violation. At the time of initial written communication with the covered entity about the complaint, the Secretary will describe the act(s) and/or omission(s) that are the basis of the complaint.

§ 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable administrative simplification provisions.

§ 160.310 Responsibilities of covered entities.

(a) *Provide records and compliance reports.* A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.* (1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to

ascertaining compliance with the applicable administrative simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, or if otherwise required by law.

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to §160.306 or a compliance review pursuant to §160.308 indicates noncompliance, the Secretary will attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity and provide the covered entity an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§160.408 and 160.410 of this part. The covered entity must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under §160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity of such finding in a notice of proposed determination in accordance with §160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to §160.306 or a compliance review pursuant to §160.308, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing.

§ 160.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), 1320a–7a(j), and 1320d–5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation or compliance review pursuant to this part. For purposes of this paragraph, a person other than a natural person is termed an "entity."

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the entity must designate one or more natural persons who will testify on its behalf, and must state as to each such person that person's name and address and the matters on which he or she will testify. The designated person must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the

entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the district court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are nonpublic investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) Representatives of the Secretary are entitled to attend and ask questions.

(4) A witness will have the opportunity to clarify his or her answers on the record following questioning by the Secretary.

(5) Any claim of privilege must be asserted by the witness on the record.

(6) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to objection.

(7) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the Secretary may seek enforcement of the subpoena under paragraph (a)(5) of this section.

(8) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(9)(i) The transcript will be submitted to the witness for signature.

(A) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the Secretary written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days (computed in the same manner as prescribed under §160.526 of this part) of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(B) Where, as provided in paragraph (b)(8) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days (computed in the same manner as prescribed under §160.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

(c) Consistent with §160.310(c)(3), testimony and other evidence obtained in an investigational inquiry may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 160.316 Refraining from intimidation or retaliation.

A covered entity may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

(a) Filing of a complaint under § 160.306;

(b) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under this part; or

(c) Opposing any act or practice made unlawful by this subchapter, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of protected health information in violation of subpart E of part 164 of this subchapter.

Subpart D—Imposition of Civil Money Penalties

SOURCE: 71 FR 8426, Feb. 16, 2006, unless otherwise noted.

§ 160.400 Applicability.

This subpart applies to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d–5.

§ 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity if the Secretary determines that the covered entity has violated an administrative simplification provision.

(b) *Violation by more than one covered entity.* (1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity.* A covered entity is liable, in accordance with the federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member, acting within the scope of the agency, unless—

(1) The agent is a business associate of the covered entity;

(2) The covered entity has complied, with respect to such business associate, with the applicable requirements of §§ 164.308(b) and 164.502(e) of this subchapter; and

(3) The covered entity did not—

(i) Know of a pattern of activity or practice of the business associate, and

(ii) Fail to act as required by §§ 164.314(a)(1)(ii) and 164.504(e)(1)(ii) of this subchapter, as applicable.

§ 160.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and §§ 160.406, 160.408, and 160.412.

(b) The amount of a civil money penalty that may be imposed is subject to the following limitations:

(1) The Secretary may not impose a civil money penalty—

(i) In the amount of more than $100 for each violation; or

(ii) In excess of $25,000 for identical violations during a calendar year (January 1 through the following December 31).

(2) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on

45 C.F.R. 164
(Excerpts)

PART 164—SECURITY AND PRIVACY

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Security Standards for the Protection of Electronic Protected Health Information

Subpart D [Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

AUTHORITY: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d-1320d-8), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, and 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)).

SOURCE: 65 FR 82802, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act and section 264 of Public Law 104-191.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 164.103 Definitions.

As used in this part, the following terms have the following meanings:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(C).

Hybrid entity means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(C).

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

[68 FR 8374, Feb. 20, 2003]

§ 164.104 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, or other than as a business associate of a covered entity, the clearinghouse must comply with § 164.105 relating to organizational requirements for covered entities, including the designation of health care components of a covered entity.

[68 FR 8375, Feb. 20, 2003]

§ 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) *Implementation specifications:*

(i) *Application of other provisions.* In applying a provision of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, to a hybrid entity:

(A) A reference in such provision to a "covered entity" refers to a health care component of the covered entity;

(B) A reference in such provision to a "health plan," "covered health care provider," or "health care clearinghouse," refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable;

(C) A reference in such provision to "protected health information" refers to protected health information that is created or received by or on behalf of the health care component of the covered entity; and

(D) A reference in such provision to "electronic protected health information" refers to electronic protected health information that is created, received, maintained, or transmitted by or on behalf of the health care component of the covered entity.

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this section and subparts C and E of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities;

(C) A component that is described by paragraph (a)(2)(iii)(C)(*2*) of this section does not use or disclose protected

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
		Sanction Policy (R)
		Information System Activity Review (R)
Assigned Security Responsibility	164.308(a)(2)	(R)
Workforce Security	164.308(a)(3)	Authorization and/or Supervision (A)
		Workforce Clearance Procedure
		Termination Procedures (A)
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function (R)
		Access Authorization (A)
		Access Establishment and Modification (A)
Security Awareness and Training	164.308(a)(5)	Security Reminders (A)
		Protection from Malicious Software (A)
		Log-in Monitoring (A)
		Password Management (A)
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R)
		Disaster Recovery Plan (R)
		Emergency Mode Operation Plan (R)
		Testing and Revision Procedure (A)
		Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement.	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A)
		Facility Security Plan (A)
		Access Control and Validation Procedures (A)
		Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)
Device and Media Controls	164.310(d)(1)	Disposal (R)
		Media Re-use (R)
		Accountability (A)
		Data Backup and Storage (A)
Technical Safeguards (see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R)
		Emergency Access Procedure (R)
		Automatic Logoff (A)
		Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A)
		Encryption (A)

Subpart D [Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

AUTHORITY: 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)).

§ 164.500 Applicability.

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing

protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care

costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of §164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of §164.514, creating deidentified health information or a limited data set, and fundraising for the benefit of the covered entity.

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Marketing means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Payment means:

(1) The activities undertaken by:

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible

for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary.* (1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by § 164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.* (1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-

identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under §164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.,* de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of §164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of §164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and §164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of §164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated

minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis,* and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis,* is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under § 164.524 to a parent, guardian, or other person acting *in loco parentis,* if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by § 164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by § 164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in § 164.520(b)(1)(iii)(A)-(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims.* (1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or

a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in §164.512(f)(2)(i).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002]

§164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at §164.514(b)(2)(i) has been deleted, except that the geographic information described in §164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)–(d)

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement between the covered entity and the business associate required by §164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in §164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of *business associate* in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the

information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of :

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by § 164.520(b)(1)(iii)(C) is included in the appropriate notice; and (iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.* (1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of

this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.* (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.*

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

[67 FR 53268, Aug. 14, 2002]

§ 164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: authorizations for uses and disclosures*—(1) *Authorization required: general rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(3) *Authorization required: Marketing.* (i) Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: general requirements*—(1) *Valid authorizations.* (i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance

coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(c) *Implementation specifications: Core elements and requirements—(1) Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

[67 FR 53268, Aug. 14, 2002]

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of

and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.

(a) *Standard: use and disclosure for facility directories.* (1) *Permitted uses and disclosure.* Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:

(i) Use the following protected health information to maintain a directory of individuals in its facility:

(A) The individual's name;

(B) The individual's location in the covered health care provider's facility;

(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and

(D) The individual's religious affiliation; and

(ii) Disclose for directory purposes such information:

(A) To members of the clergy; or

(B) Except for religious affiliation, to other persons who ask for the individual by name.

(2) *Opportunity to object.* A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.

(3) *Emergency circumstances.* (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.

(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) *Standard: uses and disclosures for involvement in the individual's care and notification purposes.* (1) *Permitted uses and disclosures.* (i) A covered entity may, in accordance with paragraphs (b)(2) or (3) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (3), or (4) of this section, as applicable.

(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based the exercise of professional judgment, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or

disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) *Use and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: uses and disclosures for public health activities.* (1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been

recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:

(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or

(*2*) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or

(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence.* (1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes

the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(d) *Standard: Uses and disclosures for health oversight activities.* (1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) *Standard: Disclosures for judicial and administrative proceedings.*

(1) *Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protecting health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(*1*) No objections were filed; or

(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Nothwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.

(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;

(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(*3*) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;
(B) Date and place of birth;
(C) Social security number;
(D) ABO blood type and rh factor;
(E) Type of injury;
(F) Date and time of treatment;
(G) Date and time of death, if applicable; and
(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.* (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) *Standard: Uses and disclosures about decedents.* (1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes.* (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(*2*) An adequate plan to destroy the identifiers at the earliest opportunity

consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety.* (1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.

(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.

(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) *Standard: Uses and disclosures for specialized government functions.* (1) *Military and veterans activities.* (i) *Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the FEDERAL REGISTER the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Transportation may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the FEDERAL REGISTER pursuant to paragraph (k)(1)(i) of this section.

(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.*, Executive Order 12333).

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or to for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and

may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:

(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12698;

(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or

(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) *Correctional institutions and other law enforcement custodial situations.* (i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; and

(F) The administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

(6) *Covered entities that are government programs providing public benefits.* (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.

(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.

(l) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

(a) *Standard: de-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) *Implementation specifications: requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) *Implementation specifications: re-identification.* A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) *Security.* The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) *Standard: minimum necessary requirements.* In order to comply with §164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) *Implementation specifications: minimum necessary uses of protected health information.* (i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of §164.512(i) have been provided by a person requesting the information for research purposes.

(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;
(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement.*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

(f)(1) *Standard: Uses and disclosures for fundraising.* A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds

for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual; and

(ii) Dates of health care provided to an individual.

(2) *Implementation specifications: Fundraising requirements.* (i) The covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(B) is included in the covered entity's notice;

(ii) The covered entity must include in any fundraising materials it sends to an individual under this paragraph a description of how the individual may opt out of receiving any further fundraising communications.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.

(g) *Standard: Uses and disclosures for underwriting and related purposes.* If a health plan receives protected heath information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such protected health information for any other purpose, except as may be required by law.

(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) *Implementation specifications: Verification.* (i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a

public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.520 Notice of privacy practices for protected health information.

(a) *Standard: notice of privacy practices*—(1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) *Implementation specifications: content of notice*—(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."

(ii) *Uses and disclosures.* The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health

information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in §160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.

(E) A statement that other uses and disclosures will be made only with the individual's written authorization and that the individual may revoke such authorization as provided by §164.508(b)(5).

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement, as applicable, that:

(A) The covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual;

(B) The covered entity may contact the individual to raise funds for the covered entity; or

(C) A group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.

(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by §164.522(a), including a statement that the covered entity is not required to agree to a requested restriction;

(B) The right to receive confidential communications of protected health information as provided by §164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by §164.524;

(D) The right to amend protected health information as provided by §164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by §164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) *Covered entity's duties.* The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact

for further information as required by §164.530(a)(1)(ii).

(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.

(1) *Specific requirements for health plans.* (i) A health plan must provide notice:

(A) No later than the compliance date for the health plan, to individuals then covered by the plan;

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees; and

(C) Within 60 days of a material revision to the notice, to individuals then covered by the plan.

(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.

(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.

(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.

(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

(iii) If the covered health care provider maintains a physical service delivery site:

(A) Have the notice available at the service delivery site for individuals to request to take with them; and

(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and

(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.

(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.

(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.

(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:

(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;

(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and

(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and

(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by §164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§164.522 Rights to request privacy protection for protected health information.

(a)(1) *Standard: Right of an individual to request restriction of uses and disclosures.* (i) A covered entity must permit an individual to request that the covered entity restrict:

(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and

(B) Disclosures permitted under §164.510(b).

(ii) A covered entity is not required to agree to a restriction.

(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.

(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.

(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§ 164.502(a)(2)(ii), 164.510(a) or 164.512.

(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate its agreement to a restriction, if :

(i) The individual agrees to or requests the termination in writing;

(ii) The individual orally agrees to the termination and the oral agreement is documented; or

(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is only effective with respect to protected health information created or received after it has so informed the individual.

(3) *Implementation specification: Documentation.* A covered entity that agrees to a restriction must document the restriction in accordance with § 164.530(j).

(b)(1) *Standard: Confidential communications requirements.* (i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.

(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.

(2) *Implementation specifications: Conditions on providing confidential communications.*

(i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.

(ii) A covered entity may condition the provision of a reasonable accommodation on:

(A) When appropriate, information as to how payment, if any, will be handled; and

(B) Specification of an alternative address or other method of contact.

(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.524 Access of individuals to protected health information.

(a) *Standard: Access to protected health information.* (1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes;

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(iii) Protected health information maintained by a covered entity that is:

(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would be prohibited by law; or

(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) *Implementation specifications: requests for access and timely action.* (1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.

(ii) If the request for access is for protected health information that is not maintained or accessible to the covered entity on-site, the covered entity must take an action required by paragraph (b)(2)(i) of this section by no later than 60 days from the receipt of such a request.

(iii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) or (ii) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) or (ii) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.

(ii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) *Time and manner of access.* The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;

(ii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iii) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.

(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) Review of denial requested. If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

§ 164.526 Amendment of protected health information.

(a) *Standard: Right to amend.* (1) *Right to amend.* An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) *Denial of amendment.* A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under § 164.524; or

(iv) Is accurate and complete.

(b) *Implementation specifications: requests for amendment and timely action.* (1) *Individual's request for amendment.* The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for

amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) *Timely action by the covered entity.* (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for an amendment.

(c) *Implementation specifications: Accepting the amendment.* If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Making the amendment.* The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) *Informing the individual.* In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

(3) *Informing others.* The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and

(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

(d) *Implementation specifications: Denying the amendment.* If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Denial.* The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:

(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;

(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and

(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in §164.530(d) or to the Secretary pursuant to the procedures established in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).

(2) *Statement of disagreement.* The covered entity must permit the individual

to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.

(3) *Rebuttal statement.* The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.

(4) *Recordkeeping.* The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

(5) *Future disclosures.* (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.

(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.

(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.

(e) *Implementation specification: Actions on notices of amendment.* A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.

(f) *Implementation specification: Documentation.* A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by § 164.530(j).

§ 164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in § 164.506;

(ii) To individuals of protected health information about them as provided in § 164.502;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;

(iv) Pursuant to an authorization as provided in § 164.508;

(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;

(vi) For national security or intelligence purposes as provided in § 164.512(k)(2);

(vii) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5);

(viii) As part of a limited data set in accordance with § 164.514(e); or

(ix) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, for the

time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§ 164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with § 164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of

this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.530 Administrative requirements.

(a)(1) *Standard: Personnel designations.* (i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.

(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520.

(2) *Implementation specification: Personnel designations.* A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.

(b)(1) Standard: Training. A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity.

(2) *Implementation specifications: Training.* (i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;

(B) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.

(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.

(c)(1) *Standard: Safeguards.* A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2)(i) *Implementation specification: Safeguards.* A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

(d)(1) *Standard: Complaints to the covered entity.* A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart or its compliance with such policies and procedures or the requirements of this subpart.

(2) *Implementation specification: Documentation of complaints.* As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.

(e)(1) *Standard: Sanctions.* A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j) or paragraph (g)(2) of this section.

(2) *Implementation specification: Documentation.* As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.

(f) *Standard: Mitigation.* A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.

(g) *Standard: Refraining from intimidating or retaliatory acts.* A covered entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against:

(1) *Individuals.* Any individual for the exercise by the individual of any right under, or for participation by the individual in any process established by this subpart, including the filing of a complaint under this section;

(2) *Individuals and others.* Any individual or other person for:

(i) Filing of a complaint with the Secretary under subpart C of part 160 of this subchapter;

(ii) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under Part C of Title XI; or

(iii) Opposing any act or practice made unlawful by this subpart, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of the opposition is reasonable and does not involve a disclosure of protected health information in violation of this subpart.

(h) *Standard: Waiver of rights.* A covered entity may not require individuals to waive their rights under § 160.306 of this subchapter or this subpart as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.

(i)(1) *Standard: Policies and procedures.* A covered entity must implement policies and procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart. The policies and procedures must be reasonably designed, taking into account the size of and the type of activities that relate to protected health information undertaken by the covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.

(2) *Standard: Changes to policies or procedures.* (i) A covered entity must

change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart;

(ii) When a covered entity changes a privacy practice that is stated in the notice described in § 164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with § 164.520(b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or

(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.

(3) *Implementation specification: Changes in law.* Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by § 164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with § 164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.

(4) *Implementation specifications: Changes to privacy practices stated in the notice.* (i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:

(A) Ensure that the policy or procedure, as revised to reflect a change in the covered entity's privacy practice as stated in its notice, complies with the standards, requirements, and implementation specifications of this subpart;

(B) Document the policy or procedure, as revised, as required by paragraph (j) of this section; and

(C) Revise the notice as required by § 164.520(b)(3) to state the changed practice and make the revised notice available as required by § 164.520(c). The covered entity may not implement a change to a policy or procedure prior to the effective date of the revised notice.

(ii) If a covered entity has not reserved its right under § 164.520(b)(1)(v)(C) to change a privacy practice that is stated in the notice, the covered entity is bound by the privacy practices as stated in the notice with respect to protected health information created or received while such notice is in effect. A covered entity may change a privacy practice that is stated in the notice, and the related policies and procedures, without having reserved the right to do so, provided that:

(A) Such change meets the implementation specifications in paragraphs (i)(4)(i)(A)–(C) of this section; and

(B) Such change is effective only with respect to protected health information created or received after the effective date of the notice.

(5) *Implementation specification: Changes to other policies or procedures.* A covered entity may change, at any time, a policy or procedure that does not materially affect the content of the notice required by § 164.520, provided that:

(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and

(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.

(j)(1) *Standard: Documentation.* A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation required by

paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

(k) *Standard: Group health plans.* (1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and (i) of this section, to the extent that:

(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and

(ii) The group health plan does not create or receive protected health information, except for:

(A) Summary health information as defined in §164.504(a); or

(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with §164.504(f).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002]

§164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in §164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with §164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with §164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research; or

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with §164.508 if, after the compliance date, informed consent is sought from an individual participating in the research.

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this subpart, a covered entity, other than a small health plan, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§164.502(e) and 164.504(e) consistent with the requirements, and only for such time, set forth in paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance*—(1) *Qualification.* Notwithstanding other sections of this subpart, a covered entity, other than a

small health plan, is deemed to be in compliance with the documentation and contract requirements of §§ 164.502(e) and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to October 15, 2002, such covered entity has entered into and is operating pursuant to a written contract or other written arrangement with a business associate for such business associate to perform functions or activities or provide services that make the entity a business associate; and

(ii) The contract or other arrangement is not renewed or modified from October 15, 2002, until the compliance date set forth in § 164.534.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section, shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after the compliance date set forth in § 164.534; or

(ii) April 14, 2004.

(3) *Covered entity responsibilities.* Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002]

§ 164.534 Compliance dates for initial implementation of the privacy standards.

(a) *Health care providers.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 14, 2003.

(b) *Health plans.* A health plan must comply with the applicable requirements of this subpart no later than the following as applicable:

(1) *Health plans other han small health plans.* April 14, 2003.

(2) *Small health plans.* April 14, 2004.

(c) *Health clearinghouses.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 14, 2003.

[66 FR 12434, Feb. 26, 2001]

PARTS 165–199 [RESERVED]